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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,497	10/11/2000	Richard F Selden	10278-022001	5761

26161 7590 11/25/2003

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BOSTON, MA 02110

EXAMINER	
NASHED, NASHAAT T	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.**	**Applicant(s)**	
	09/686,497	SELDEN ET AL.	
	Examiner	**Art Unit**	
	Nashaat T. Nashed	1652	

--The MAILING DATE of this communication appears on the c ver sheet with th correspondence addr ss --

THE REPLY FILED 10/24/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-15 and 26-32*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER

Claims 1-14 and 26-32 are under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicants are required to comply with the sequence rule by filing a new sequence listing, CRF, and an amendment to delete the paper copy of the sequence listing and enter the new one along with a statement indicating that the CRF and the paper copy of the sequence listing are identical and contain no new matter. On page 33, line 3 from the bottom, an amino acid sequence is not identified with a sequence identification number.

In response to the above objection, applicants reiterated their previous arguments that the sequence contains only two arginine residues, and therefore, it is shorter than four amino acid.

Applicants arguments filed 10/24/03 have been fully considered, but they are found unpersuasive. The amino acid sequence in question consists of 5 amino acid, i. e., X-Arg-X-X-Arg wherein X is any amino acid. According to the sequence rules, any sequence disclosed in an application which is longer than four amino acid residues should be identified by a sequence identification number and be listed in the sequence listing in both the paper form and CRF. Applicant must perfect their compliance with sequence rule.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 26-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-135 of copending Application No. 09/407,605 ('605) for the reasons set forth in the prior Office action, paper number 13.

Applicants remarks regarding these rejections filed 10/24/03 are noted, and the rejection will remain on record until further action by the applicants.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seed (IDS (paper number 12): Ref. AG: WO 96/09378) in view of the prior art as exemplified by Kim *et al.* [IDS (paper number 4): Ref AQ: Gene 199, 293-301 (1997)], Morgan *et al.* [Pediatr. Nephrol. (1987) 1, 536-539], Bishop *et al.* (Proc. Natl. Acad. Sci. U. S. A. 83, 4859-4863), and [Nucleic Acid Research 20, 2111-2118 (1992)] for the reasons set forth in the prior Office action, paper number 13.

In response to the above rejections, applicants limit their claim to a human α-galactosidase and agreed that the examiner has established a *prima facie* case of obviousness, and argue that the prior art teaches away from the claimed invention.

Applicants' arguments filed 10/24/03 have been fully considered but they are not deemed to be persuasive. The examiner disagrees. Applicant argument regarding that the prior art does not teach human modified genes that includes viral protein such as HIV envolpe glycoprotein is not particularly persuasive. Although the gene encoding HIV

envolpe glycoprotein is a viral gene, it is naturally expressed in human cells using the human enzymes and ribosomes. The prior art of record clearly teaches optimizing the colones of the gene encoding HIV envolpe glycoprotein leads to enhanced expression in mammalian cells, see Seed. The cautionary note provided by Seed does not teach away from the claimed invention because the optimized gene encoding HIV envolpe glycoprotein, a gene naturally expressed in mammalian cells, displays enhanced expression in mammalian cells. There is no experimental evidence suggest other wise. Kim *et al.* work only with human genes and writes:
"Reengineering the coding sequence to match to the codons frequently found in human genes is beneficial to achieve high-level of expression. Recent reports clearly support this. Altering the coding sequence of the HIV envelope glycoprotein gp120 and jellyfish green fluorescent protein gene to human prevalent codons results in substantial increase in expression efficiency (Haas *et al.* 1996; and Zolotukhin *et al.* 1996." (See Kim *et al.*, the last paragraph on page 299). Although Seed has a cautionary remark regarding the over use of human preferred codon containing CpG, Kim *et al.* have none. The Kim *et al.* reference (publication date (10/15/97) is published at a later date than the Seed reference (publication data 3/27/97). From the statement quoted by Kim *et al.* and cited above, Kim *et al.* were aware of Seed's work and results, and have not supported such a caution.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

N Shed

Nashaat T. Nashed, Ph. D.
Primary Examiner